

## REMARKS

Applicant submits this Amendment in reply to the Office Action mailed July 30, 2004.

By this Amendment, Applicant has cancelled non-elected claims 40-60, without prejudice or disclaimer to represent them in this application or a continuing application. Applicant has amended claim 9 to correct an inadvertent dependency error, and added new claims 61-107 to further define the claimed invention. The originally filed specification, drawings, and claims fully support the subject matter of amended claim 9 and new claims 61-107. No new matter has been introduced.

Before this Amendment, claims 1-60 were pending, with claims 40-60 having been withdrawn from consideration. After this Amendment, claims 1-39 and 61-107 are pending. Claims 1, 22, 61, and 82 are independent claims.

On page 2 of the Office Action, claims 9 was rejected under 35 U.S.C. § 112, second paragraph, for alleged indefiniteness. Applicant has amended claim 9 such that it now depends from claim 8. Accordingly, Applicant respectfully requests withdrawal of the Section 112, second paragraph, rejection.

On pages 2-4 of the Office Action, claims 1-4, 8-10, 14-19, 22-26, 31-34, 38, and 39 were rejected under 35 U.S.C. § 102(b) as being anticipated by Japanese Patent Application Publication No. H06-343599 to Mitsuru ("Mitsuru"). Applicant respectfully traverses this rejection.

Mitsuru does not disclose every aspect of each of independent claims 1 and 22, as required by Section 102. For example, each of independent claims 1 and 22 recites, among other aspects, "wherein the distal assembly has an open configuration and a

closed configuration with a profile larger than a diameter of the channel of the endoscope." Mitsuru does not disclose at least this aspect of the invention either alone or in combination with the other aspects of each of claims 1 and 22.

On page 3 of the Office Action, the Examiner alleges that either flexible tubular part 10 or operating wire part 20 of Mitsuru corresponds with the elongate member of claims 1 and 22, that light guide part 50 corresponds with the endoscope of claims 1 and 22, and that forceps section 70 corresponds with the distal assembly of claims 1 and 22. Mitsuru, however, discloses that the disclosed forceps device, including light guide part 50, inserts into a channel of an endoscope. In particular, the Abstract of Mitsuru discloses that "[t]his forceps device for the endoscope has a flexible part 10 which is insertable into a channel for insertion of the endoscope." (Emphasis added). Thus, light guide part 50 cannot correspond to the endoscope of claims 1 and 22, as it inserts into a channel of an endoscope. Accordingly, since light guide part 50 does not correspond to the endoscope of claims 1 and 22, Mitsuru fails to disclose or suggest any relative size of the profile of the forceps section 70 with a diameter of a channel of an endoscope. For at least this reason, Applicant respectfully requests withdrawal of the Section 102(b) rejection.

On pages 2-4 of the Office Action, claims 1-4, 8-10, 14-19, 22-26, 31-34, 38, and 39 were alternatively rejected under 35 U.S.C. § 103(a) as being unpatentable over Mitsuru. Applicant respectfully traverses this rejection.

To establish a *prima facie* case of obviousness under 35 U.S.C. §103, three basic criteria must be satisfied. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of

ordinary skill in the art, to modify a reference or to combine references. Second, there must be a reasonable expectation of success. Third, the prior art reference (or references when combined) must teach or suggest all the claim elements. M.P.E.P. § 2143. Moreover, the teaching or suggestion to make the claimed combination must be found in the prior art, and not in applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

As set forth above, each of independent claims 1 and 22 recite, among other aspects "wherein the distal assembly has an open configuration and a closed configuration with a profile larger than a diameter of the channel of the endoscope." Also as set forth above, Mitsuru does not disclose or suggest at least this aspect of the invention either alone or in combination with the other aspects of each of claims 1 and 22. Accordingly, the third requirement for establishing a *prima facie* case of obviousness has not been established with respect to independent claims 1 and 22, and hence also its dependent claims 2-4, 8-10, 14-19, 23-26, 31-34, 38, and 39, that were alternatively rejected under Section 103(a).

Moreover, with regard to at least some of dependent claims 2-4, 8-10, 14-19, 23-26, 31-34, 38, and 39, the Office Action did not reasonably specify which portions of Mitsuru allegedly correspond to certain aspects of the claims. This failure in specificity resulted in the Office Action not making any case of unpatentability with regard to at least some of these dependent claims, let alone meet a *prima facie* case of obviousness as required by M.P.E.P. §§ 706.02(j), 2143. The M.P.E.P. instructs that "[w]henever, on examination, any claim or a patent is rejected, or any objection... made,' notification of the reasons for rejection and/or objection together with such information and

references as may be useful in judging the propriety of continuing the prosecution (35 U.S.C. § 132) should be given." M.P.E.P. § 707. "For rejections under 35 U.S.C. § 103, the way in which a reference is modified or plural references are combined should be set out." Id.

For example, the Office Action did not specify which elements in the Mitsuru device allegedly satisfy the structural relationships set forth in at least claims 19 and 39, including that the profile of the claimed jaw members is smaller than a diameter of the tube. The Office Action provided no structure in Mitsuru allegedly corresponding to the subject matter of claim 31. With regard to claim 3 (and presumably claim 24), the Office Action simply states that "Mitsuru discloses a member near the proximal end of the elongate member at the handle which inherently acts as a stop," yet Applicant has not been able to identify which portion of Mitsuru "inherently acts as a stop." Thus with regards to at least claims 3, 19, 24, 31, and 39, Applicant asserts that the third criteria for establishing a *prima facie* case of obviousness has not been met.

On pages 4-5 of the Office Action, claims 5, 6, 11-13, 20, 21, 27-30, and 35-37 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Mitsuru. Applicant respectfully traverses this rejection.

As set forth above, each of independent claims 1 and 22 recite, among other aspects, "wherein the distal assembly has an open configuration and a closed configuration with a profile larger than a diameter of the channel of the endoscope." Also as set forth above, Mitsuru does not disclose or suggest this aspect of the invention either alone or in combination with the other aspects of each of claims 1 and 22. Accordingly, the third requirement for establishing a *prima facie* case of

obviousness has not been established with respect to independent claims 1 and 22, and hence its dependent claims 5, 6, 11-13, 20, 21, 27-30, and 35-37, that were rejected under Section 103(a).

Moreover, with regard to claims 5, 6, and 27-29, the Examiner admits that "Mitsuru fails to disclose the details of the handle with the slide." The Examiner then asserts, however, that "it is old and well known in this art to so construct handles for reliably and smoothly activating surgical end effector." With regard to claims 7, 11-13, 20, 21, 30, and 35-37, the Examiner admits that "Mitsuru fails to disclose the details of the elongate member," yet again asserts that "it is old and well known in this art to so construct elongate members for reliably and smooth activating surgical end effectors." These are improper motivations for each of their respective sets of claims because neither motivation is clear and particular, as required by In re Dembiczak, 175 F.3d 994, 999 (Fed. Cir. 1999), nor found in the prior art, as required by In re Vaeck, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991). Indeed, the Examiner has not provided any evidence to support either the alleged motivation or the alleged disclosure of the claims. Instead, the Examiner has taken Mitsuru, and used the present invention, along with hindsight, as a roadmap to come to the obviousness rejection with no evidentiary basis. This is not a motivation at all, but is simply an impermissible conclusory statement that adding the respective aspects of each claim to Mitsuru will allegedly result in the claimed invention.

Indeed, if the Examiner is taking official notice in rejecting the claims, Applicant asserts that the Examiner has not met the requirements for meeting official notice as set forth in M.P.E.P. § 2144.03. The M.P.E.P. instructs:

Any rejection based on assertions that a fact is well-known or is common knowledge in the art without documentary evidence to support the examiner's conclusion should be judiciously applied. Furthermore, as noted by the court in *Ahlert*, any facts so noticed should be of notorious character and serve only to "fill in the gaps" in an insubstantial manner which might exist in the evidentiary showing made by the examiner to support a particular ground of rejection. It is never appropriate to rely solely on common knowledge in the art without evidentiary support in the record as principal evidence upon which a rejection was based.

Applicant respectfully traverses the assertion of official notice.

For example, the purpose of at least certain of the various elements and their relationships in claims 5, 6, and 27-29 go well beyond simply "reliably and smoothly activating surgical end effectors." In addition, with regard to the rejections of claims 7, 11-13, 20, 21, 30, and 35-37, the alleged motivation (i.e., to construct elongate members for reliably and smoothly activating surgical end effectors) is not related to the subject matter of at least some of the claims, and does not provide motivation to modify Mitsuru such that the subject matter of each of the claims is rendered obvious. For example, claims 7 and 30 include an attachment cup; claims 11 and 35 include a needle and a hub; claims 12 and 36 include a needle point; claim 13 includes a medical device; claim 20 includes a spring; and claim 37 includes a medical instrument. The Office Action therefore does not set forth a *prima facie* case of obviousness for at least these claims.

For at least the aforementioned reasons, Applicant respectfully requests withdrawal of the Section 103(a) rejections. If the Examiner, however, insists on maintaining the claim rejection under 35 U.S.C. §103(a) based on the unsupported allegations about certain subject matter being "old and well known in this art," Applicant

respectfully requests the Examiner provide documentary evidence supporting these allegations so that Applicant will be able to respond in kind.

Applicant further submits that claims 2-21 and 23-39 depend either directly or indirectly from one of independent claims 1 and 22, and are therefore allowable for at least the same reasons that their respective independent claims are allowable. In addition, at least some of the dependent claims recite unique combinations that are neither taught nor suggested by the cited references and therefore at least some also are separately patentable.

Applicant also presents new claims 61-107. Insofar as the Examiner may apply Mitsuru to new claims 61-107, Applicant responds as follows.

Mitsuru does not disclose every aspect of each of independent claims 61 and 82, as required by Section 102. For example, each of independent claims 61 and 82 recites, among other aspects, "wherein the distal assembly has an open configuration and a closed configuration with a profile larger than a diameter of the channel of the endoscope." These aspects are neither disclosed nor suggested by Mitsuru for at least the reasons set forth above.

Moreover, each of independent claims 61 and 82 also recites, among other aspects, a "distal assembly [ ] adapted to be exterior to the channel [of the endoscope] when the endoscope is inserted into the body, the distal assembly including a tube and an end effector having a profile in the closed configuration that is smaller than a profile of a lumen of the tube." Mitsuru does not disclose at least this aspect of the invention either alone or in combination with the other aspects of each of claims 61 and 82.

On page 3 of the Office Action, the Examiner alleges that either flexible tubular part 10 or operating wire part 20 of Mitsuru corresponds with the elongate member, that light guide part 50 corresponds with the endoscope, and that forceps section 70 corresponds with the distal assembly. Even assuming *arguendo* that this is correct, Mitsuru still does not disclose or suggest "an end effector having a profile in the closed configuration that is smaller than a profile of a lumen of the tube," as set forth in each of claims 61 and 82. Indeed, even if any of portions 10, 40, or 50 could correspond to the tube of claims 61 and 82, the forceps section 70 does not have a profile smaller than a profile of a lumen of any of these alleged tubes. For at least this reason, Applicant respectfully asserts that independent claims 61 and 82, and their respective dependent claims 62-81 and 83-107, are patentable over Mitsuru.

In view of the foregoing amendments and remarks, Applicant respectfully requests reconsideration and reexamination of this application and the timely allowance of the pending claims.

The Office Action contains characterizations of the claims and the related art with which Applicant does not necessarily agree. Unless expressly noted otherwise, Applicant declines to subscribe to any statement or characterization in the Office Action.

In discussing the specification, claims, and drawings in this Amendment, it is to be understood that Applicant is in no way intending to limit the scope of the claims to any exemplary embodiments described in the specification and/or shown in the drawings. Rather, Applicant is entitled to have the claims interpreted broadly, to the maximum extent permitted by statute, regulation, and applicable case law.

Please grant any extensions of time required to enter this Amendment and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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